The cost-effectiveness of screening for type 2 diabetes

CDC Diabetes Cost-Effectiveness Study Group

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Screening for type 2 diabetes mellitus using a fasting plasma glucose test (FPGT) confirmed by an oral glucose tolerance test (OGTT) (for persons testing positive to the first test).

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
A hypothetical population, aged 25 years and above, modelled on the general US population without diagnosed diabetes and of whom a percentage (forming a cohort of 10,000) have undiagnosed type 2 diabetes.

Setting
Community. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness estimates were based on studies published between 1981 and 1997. Prices were adjusted for inflation and costs were expressed in 1995 dollars.

Source of effectiveness data
Data were obtained from published clinical trials, epidemiological studies and population surveys.

Modelling
A semi-Markov Monte Carlo simulation model was used to estimate the lifetime costs and benefits of a screening programme and early treatment of those patients diagnosed by this means. A hypothetical population without clinically diagnosed diabetes was assigned to either screening or standard clinical practice. The model assigned initial characteristics to each successive individual such as age, sex and ethnic group. Following screening the possible outcomes were, positive screen without diabetes, negative screen without diabetes, positive screen with diabetes and negative screen with diabetes. Individuals in the latter categories were then entered into the disease progression model. Disease states for 3 major microvascular complications were included: retinopathy, nephropathy and neuropathy. Each state began with the possibility of no disease and included the risk of death which was a competing risk between each complication. Progression through these states followed a Markov model with a 1 year cycle and continued until death or age 95. The simulation continued until a cohort of 10,000 had been through the disease progression model.
Outcomes assessed in the review
The following outcomes were assessed by review: the duration of undiagnosed diabetes, prevalence of undiagnosed diabetes, HbA1c values at onset of disease, at clinical diagnosis and at screened diagnosis; the reduction in HbA1c levels brought about by diet-only treatment and the rate of increase in HbA1c levels over time. Transition probabilities for the 3 disease states from having no disease to the first state and from 1 state to the next were as follows.

Retinopathy: from no retinopathy to non-proliferative retinopathy, from non-proliferative to proliferative retinopathy and from that to macular edema. Blindness from both proliferative retinopathy and macular edema.

Nephropathy: from no nephropathy to microalbuminuria, from that to proteinuria and from that to end-stage renal disease.

Neuropathy: from no neuropathy to symptomatic neuropathy and from that to lower extremity amputation.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
An expert panel, convened for the study, selected and interpreted the parameters used in the model.

Number of primary studies included
Eight primary studies were included.

Methods of combining primary studies
Primary studies were not combined. Each study was used to estimate a separate input into the model.

Investigation of differences between primary studies
Not relevant.

Results of the review
9-12 years (mean: 10.5 years) elapse between the onset and clinical diagnosis of diabetes. The prevalence of undiagnosed diabetes was estimated at 3.2% of the US population between 20 and 74 years. The HbA1c value was assumed to be 6.8% at onset of diabetes and 8.9% at clinical diagnosis. Under screening it was assumed to be 7.8% at diagnosis. The reduction in HbA1c after 1 year's treatment with diet alone was 2.1 percentage points. The rate of increase in HbA1c levels with diet treatment was 0.156 percentage points per year. Transition probabilities (hazard rates) for disease states were as follows.

Retinopathy:non-proliferative retinopathy 0.021 - 0.129, depending on the duration of diabetes and race or ethnicity; proliferative retinopathy 0.002 - 0.026 depending on duration of diabetes and race or ethnicity; macular edema, 0.047 - 0.095 depending on duration of diabetes and race or ethnicity; blindness from proliferative retinopathy, 0.088 if untreated and 0.015 if treated; blindness from macular edema, 0.050 if untreated and 0.033 if treated.
Nephropathy: microalbuminuria, 0.010 - 0.027, depending on duration of diabetes and race or ethnicity; proteinuria 0.157; end-stage renal disease, 0.004 - 0.074 depending on duration of diabetes.

Neuropathy: symptomatic neuropathy, 0.003 - 0.014 depending on duration of diabetes and race or ethnicity; lower extremity amputation, 0.028 - 0.467 depending on duration of diabetes.

**Measure of benefits used in the economic analysis**

The measures of benefit were life years gained and QALYs gained. QALY values were given as 1 for life without major complications, 0.69 for blindness, 0.61 for ESRD and 0.8 for lower extremity amputation. Reference was made to the literature used for the model input assumptions but no other explanation was given of QALY valuations. The model used was a semi-Markov Monte Carlo simulation where the Markov method was used to model disease progression in the hypothetical individuals in the simulation who truly developed diabetes (whether screened or not) and then entered simultaneously a disease state model for 3 complications. A simple Monte Carlo model assessed probabilities of developing diabetes and date of diagnosis through screening or non-screening. The model was used to assess lifetime benefits. Benefits were discounted at 3%. Subgroups were analysed separately. The sample was divided by age into 6 groups and by ethnic group so that African Americans were analysed separately and also further subdivided into age groupings.

**Direct costs**

Costs were discounted at 3%. The price year used was 1995. The cost boundary assumed was that of a lifetime single payer such as Medicare. Cost assumptions used in the model were based on a survey of literature in the same way as clinical assumptions. Eight references were quoted for assumptions on resource use. Quantities and costs were not analysed separately. The costs included as inputs to the model were physician time, making assumptions about the number of physician visits needed for each state, cost of screening tests, self monitoring, drugs and insulin, and costs of complications.

**Indirect Costs**

Not considered.

**Currency**

US dollars ($).

**Sensitivity analysis**

One-way analyses were carried out on the following: using a different screening test (HbA1c test instead of FPGT), on the sensitivity and specificity of screening test, on the length of the pre-diagnosis interval, on the prevalence of undiagnosed diabetes, on the glycemic level control, on initial treatment costs, on the cost of physician's time for the screening test and on the discount rate used for costs and benefits.

**Estimated benefits used in the economic analysis**

For all ages 25 years and above, years of life were increased by 0.02 years (one week). Life years from disease onset to death in the unscreened sample were 12.33 and in the screened sample were 12.35. The lifetime cumulative incidence of ESRD was reduced by 26%, blindness by 35% and LEA by 22% leading to a gain in QALYs of 0.08, 0.27, and 0.15 respectively. QALYs from onset of disease in the unscreened sample were 12.14 and in the screened sample 12.22. In some sub-groups the effect was greater. The 25 to 34 year age group in the total sample had a 0.13 gain in lifeyears and 0.35 gain in QALYs 0.35. The African American group aged between 25 and 34 had a 0.15 gain in life years and 0.4 gain in QALYs. Sensitivity analysis showed that the model was moderately sensitive to the performance of the screening test. It was sensitive to assumptions about the length of the pre-diagnosis interval, the prevalence of undiagnosed diabetes and the intensity of glycemic control therapy. Discount rate changes also affected cost effectiveness results.
Cost results
The lifetime costs of treatment per person for the total unscreened cohort were $46,219. For the screened cohort the lifetime costs were $49,608 plus screening costs of $1,166 per diagnosed diabetic, an increase in lifetime costs of $4,555. In the sub-group aged 25-34 lifetime treatment costs for the unscreened group were $97,360 and for the screened cohort were $96,085 plus screening costs of $5,933 (an increase of $4,658). In the African American group aged 25-34 lifetime treatment costs for the unscreened group were $111,686. For the unscreened cohort treatment costs were $106,147 plus $5,864 screening costs (an increase of $325).

Synthesis of costs and benefits
Over the whole sample the cost per life year gained was $236,449 and cost per QALY gained was $56,649. In the 25-34 age group the cost per life year gained was $35,768 and cost per QALY gained was $13,376. In the African American subgroup aged 25-34 the cost per life year gained was $2,219 and cost per QALY gained $822.

Authors' conclusions
Early diagnosis through screening does result in gains in life years and QALYs. Costs may be in the range of acceptable cost effectiveness. The results are more marked in the younger age groups and among African Americans and selection of target populations should take this into account.

CRD COMMENTARY - Selection of comparators
The choice of comparators is clear.

Validity of estimate of measure of benefit
A complicated model such as this one is likely to be affected by variations in input assumptions. Given the lack of evidence of a systematic search of the literature, the extent to which all relevant studies were included is not clear.

Validity of estimate of costs
Cost estimates were not sufficiently detailed to be generalisable to another country or health care system. Costs were not reported separately from prices. Only direct medical costs were determined in the analysis and costs to others in society, such as patients, could usefully have been included.

Other issues
Results might be biased as the review does not appear to have been systematic. The cost data may not be generalisable to other settings or countries.

Implications of the study
A more reliable assessment of the relative benefits would come from a Randomized controlled trial.

Source of funding
None stated.

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